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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,190

Applicant(s)

MIKI ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-17 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on NONE is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 08/27/2004 has been entered.

Claims 1-5 have been canceled. Claims 6-17 have been amended, are pending and currently under consideration.

Claim Objections

Claim 14 is objected to because of the following informalities: The word "mantle" is misspelled in line 5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

The rejection of claims 8,9 and 11-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn with respect to the phrase "substitutes which relate to pigment formation". Applicant has replaced the phrase "substitutes which relate to pigment formation".

Enablement

The rejection of claims 6-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's arguments have been thoroughly considered and are partially persuasive as set forth below.

1) With respect to the aspect of the rejection on the basis that the specification does not enable making a transgenic mollusk that secretes a colored protein into the pearl, the rejection is maintained. Applicant's arguments are not considered persuasive and the rejection is maintained for reasons of record set forth on pages 4-6 of the previous office action mailed 08/29/2003.

Applicant has argued that the skilled artisan would know how to make and use the invention of producing a colored pearl-producing, transgenic mollusk based on the disclosure in the specification. Applicant submits that the inventors isolated and sequenced a gene encoding a protein that is a scaffold for a crystal layer of a pearl and is secreted from the mantle (it is presumed Applicant is referring to the prism protein gene and/or the mantle protein gene). Applicant argues that the inventors discovered the possibility of inserting a pigment gene into the crystal layer framework protein gene (presumably the prism protein gene and/or mantle protein gene) to change the color of the pearl.

In response, the claims are not limited to any particular gene, including the prism protein gene or mantle protein gene, and the claims only require expression of and do not require secretion of the pigment protein. The claims are merely drawn to a mollusk whose genome comprises any promoter operably linked to a pigment-encoding gene wherein the gene is

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expressed in the mantle. Claim 17 limits the promoter to the adenoviral promoter and prism protein promoter. While the specification teaches expression of GFP in the mantle of mollusks comprising the GFP gene operably linked to an adenoviral CAG promoter (Example 1, pages 10-11; for description of pAxCawt vector see Niwa, 1991), it does not demonstrate secretion from the mantle into the pearl and gives no guidance with respect to how to permit or to signal secretion of the GFP from the mantle into the pearl. Without secretion of the colored protein into the pearl, one cannot obtain a colored pearl. The skilled artisan would not know how to use the claimed mollusk that merely expresses a pigment in th mantle and does not secrete it into the pearl. Furthermore, the specification does not demonstrate secretion of GFP using the promoters of the prism protein and mantle protein genes. The guidance with respect to the structure of the transgenes used is vague and confusing such that it cannot be determined how to make a fusion protein comprising the prism or mantle proteins or parts thereof such that they are secreted. The specification at page 11 teaches fusing the GFP gene to the prism protein promoter without the prism-protein-encoding portion of the gene (refer to page 11, lines 11-24). Furthermore, the specification states, "...it is thought that pearls which emit fluorescence are formed because GFP is fused with the prism protein constituting the pearls" (page 12, lines 11-12). Because it is not clear based on the description of how to make the vectors comprising GFP operably linked to any promoter including the adenoviral, prism protein or mantle protein gene promoters, and it is not clear that the vector actually comprises the prism protein or its secretion signal sequence, and because the specification does not teach that the protein made from the recombinant gene is secreted, and further, because the specification merely contemplates that "it is thought" that the

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pearls emit fluorescence, the specification fails teach how to make a transgenic pearl-producing mollusk that has a pigment secreted into the pearl so as to make a colored pearl.

2) The rejection on the grounds that the specification does not enable making and using all species of mollusks is withdrawn in light of Applicant's amendments to claims, which limit the claims to pearl-producing mollusks.

3) The rejection with respect to the breadth of fusion proteins encompassed by claims 14 and 17 is withdrawn in light of the amendments to the claims. Claims are no longer drawn to the nacreous layer protein gene, prism layer skeleton protein gene or the calcium carbonate crystallizing gene.

4) Claims are drawn to transgenic mollusks expressing a pigment gene in the mantle. The claims do not require that the pigment be secreted into the pearl. The intended use of the claimed mollusk is to make a colored pearl. A transgenic mollusk merely expressing a pigment gene in the mantle does not necessarily produce a colored pearl. As such, one of skill in the art at the time of filing would not know how to use a mollusk merely expressing a pigment gene in the mantle as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-17 are under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained in part as set forth below.

1) The previous rejection of claims 6-9 as being indefinite for use of the term “desired” is withdrawn in light of Applicant’s amendment to the claims deleting this term.

2) The rejection of 6-9 as being indefinite because it appears that practice of the claims would not result in production of the mollusks of claims 10 or 11 is maintained (see paragraph bridging pages 8-9 of the previous office action). Applicant has argued that the amendments to the claims have made the claims less confusing and that the methods of claims 6-9 will result in the mollusks of claims 10 and 11. This argument is not persuasive. The mollusk of claims 10 and 11 are limited to those that express a fluorescent protein in the mantle. Claims 6-9 are not so limited and include any gene related to color. The method of making a mollusk that expresses B-galactosidase will not result in a mollusk with fluorescence emission in the mantle as claimed.

3) The rejection on the grounds that the phrase “microinjecting into gonad of male and/or female of mollusk a recombinant vector into which a foreign gene to be introduced” is unclear is withdrawn in light of Applicant’s amendment to the claim removing this phrase.

4) The rejection of claim 10 as being indefinite is maintained. Applicant has not provided any argument specific to this grounds of rejection. The claim is directed to foreign genes that encode substances which relate to pigment formation, the expression of which results in emission of fluorescence (see claim 10, line 7). The specification has defined substances that relate to pigment formation as those substances that catalyze a reaction resulting in pigment formation (such as, for example, β -galactosidase). Fluorescent proteins, which result in emission of fluorescence appear to be different from substances that relate to pigment formation given the definitions provided by the instant specification and the prior art. Accordingly, it appears that the instant specification has not provided a definition for a substance relating to pigment

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formation, the expression of which results in emission of fluorescence. Appropriate correction is required. Claims 6-7, 9, 12-14 and 17 depend from claim 10.

5) The rejection of claim 11 as being indefinite is maintained. Applicant has not provided any argument specific to this grounds of rejection. The phrase "...comprising a recombinant vector comprising a nucleic acid construct and a promoter that is operably linked to a foreign gene..." can be interpreted that the "nucleic acid construct" is separate and distinct from "a promoter that is operably linked to a foreign gene". If the nucleic acid is separate from the promoter that is operably linked to a foreign gene, the fluorescence (line 5) does not relate back to the foreign gene, but relates back to the nucleic acid construct. Appropriate correction is required. Claims 12-17 depend from claim 11 and are thus included in this rejection.

6) The rejection of claim 11 on the grounds that the term "substitutes" is indefinite is withdrawn in light of Applicant's amendment to the claim.

New grounds of rejection based on Applicant's amendments to the claims appears below:

7) Claims 6-17 are unclear because of the phrase "a foreign gene encoding pigments or encoding a foreign gene encoding enzyme with catalyze reactions forming pigments" in claim 10 and the phrase "a foreign gene encoding pigment protein or a foreign gene encoding enzyme with catalyze reactions forming pigments or encoding pigment genes themselves" in claim 11. The phrases are wholly unclear. They are run-on phrases and it cannot be determined if the claims are referring to a foreign gene encoding a foreign gene encoding an enzyme or if it is separately referring to two, separate foreign genes. The use of punctuation might help clarify the claim. The phrase in claim 11 is redundant because it states "...a foreign gene encoding pigment protein..." and "...or encoding pigment genes themselves..." in the same phrase. Furthermore,

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genes cannot encode genes as set forth in the phrase of claim 11. Claims 6-9, 12-14 and 17 depend from claim 10. Claims 12-17 depend from claim 11.

8) Claim 17 is unclear as it refers to the “adenoviral promoter” and the “prism protein promoter”. Adenovirus and prism proteins themselves do not have promoters. Adenoviral genes and the prism protein genes have promoters.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632

Joe Woutard
AU1632